

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

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*Ex parte*

GARY LOWELL ENGEL and BENJAMIN ALAN DISEROAD

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Appeal 2008-0406  
Application 10/477,192  
Technology Center 1600

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Decided: August 29, 2008

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Before TONI R. SCHEINER, DEMETRA J. MILLS, and LORA M. GREEN,  
*Administrative Patent Judges.*

SCHEINER, *Administrative Patent Judge.*

**DECISION ON APPEAL**

This is an appeal under 35 U.S.C. § 134 involving claims to two different crystalline forms of the difumarate salt of 1-(Indole-6-carbonyl-D-phenylglyciny)-4-(1-methylpiperidin-4-yl) piperazine. The Examiner has rejected the claims as anticipated, and as unpatentable under the doctrine of

obviousness-type double patenting. We have jurisdiction under 35 U.S.C. § 6(b).

We reverse.

#### STATEMENT OF THE CASE

Claims 3, 5, and 17 stand rejected under the doctrine of obviousness-type double patenting as unpatentable over U.S. Patent 6,946,467 B2 to Liebeschuetz et al., issued September 20, 2005 (hereinafter U.S.'467).

Claim 17 stands rejected under 35 U.S.C. § 102(e) as anticipated by WO 01/96323 A1 (International Patent Application of Liebeschuetz et al., published December 20, 2001).

Claims 3, 5, and 17, together with allowed claim 4, from which claim 17 depends, read as follows:

3. 1-(Indole-6-carbonyl-D-phenylglyciny1)-4-(1-methylpiperidin-4-yl) piperazine Difumarate in crystalline form having an X-ray powder diffraction pattern with sharp, intense peaks at  $2\theta = 6.280, 7.820$  and  $19.513$ .
4. 1-(Indole-6-carbonyl-D-phenylglyciny1)-4-(1-methylpiperidin-4-yl) piperazine Difumarate in crystalline form having an X-ray powder diffraction pattern with sharp, intense peaks at  $2\theta = 8.833, 20.810$  and  $23.824$ .
5. A pharmaceutical composition, which comprises the difumarate salt as claimed in Claim 3 together with at least one pharmaceutically acceptable carrier or excipient.
17. A pharmaceutical composition, which comprises the difumarate salt as claimed in Claim 4 together with at least one pharmaceutically acceptable carrier or excipient.

## DISCUSSION

### *Obviousness-Type Double Patenting*

The Examiner rejected claims 3, 5, and 17 under the doctrine of obviousness-type double patenting as unpatentable over claims 1 and 2 of U.S. Patent 6,946,467 to Liebeschuetz (U.S.'467).

#### Claim 3

Claim 3 is directed to a particular crystalline form of 1-(Indole-6-carbonyl-D-phenylglyciny)-4-(1-methylpiperidin-4-yl) piperazine difumarate. The Examiner acknowledges that the subject matter of claim 3 is not claimed in U.S.'467, but contends that it “**is described** [in Example 48 B] in US'467 and is covered by the claims' scope in US'467” (Ans. 5). The Examiner argues that Appellants “could have presented separate claim(s) only covering . . . 48 B” (Ans. 6), and are “**not** entitle[d] . . . to a 2<sup>nd</sup> patent covering essentially what was explicitly described and covered in the 1<sup>st</sup> patent - without a terminal disclaimer” (*id.*).

Claim 1 of U.S.'467 is directed to a salt of 1-(Indole-6-carbonyl-D-phenylglyciny)-4-(1-methylpiperidin-4-yl) piperazine, while claim 2 is directed to a pharmaceutical composition containing the salt of claim 1, together with a pharmaceutically acceptable carrier or excipient.

There is no dispute that the patented claims are generic to claim 3 of the application, and would dominate claim 3 of the application, in that claim 3 could not be practiced without infringing the patented claims. But domination, “by itself, does not give rise to ‘double patenting’.” *In re Kaplan*, 789 F.2d 1574, 1577 (Fed. Cir. 1986); *see also In re Sarett*, 327 F.2d 1005, 1014 (CCPA 1964). A proper obviousness-type double patenting

rejection “rest[s] on the fact that a patent has been issued and later issuance of a second patent will continue protection, beyond the date of expiration of the first patent, . . . of a mere variation of that invention which would have been obvious to those of ordinary skill in the relevant art” (*Kaplan*, 789 F.2d at 1579-80 (emphasis omitted)). That being the case, “there must be some clear evidence to establish why the variation would have been obvious which can properly qualify as ‘prior art.’ Even if obviousness of the variation is predicated on the level of skill in the art, prior art evidence is needed to show what that level of skill was” at the time of the invention (*id.*).

On this record, the Examiner has not provided evidence which would establish that claim 3 of the application, which requires a particular crystalline form of the difumarate salt of 1-(Indole-6-carbonyl-D-phenylglyciny)-4-(1-methylpiperidin-4-yl) piperazine, would have been obvious over the generic salt.

Accordingly, the Examiner’s rejection of the claims under the doctrine of obviousness-type double patenting is reversed with respect to claim 3.

Claims 5 and 17

Claim 5 is directed to a composition comprising the crystalline difumarate salt of claim 3, “together with at least one pharmaceutically acceptable carrier or excipient.” Claim 17 is directed to a composition comprising the crystalline difumarate salt of claim 4, “together with at least one pharmaceutically acceptable carrier or excipient.” The Examiner acknowledges that the crystalline form required in claim 4 “is not within the teachings of Liebeschuetz” (Ans. 5).

Nevertheless, the Examiner contends that claims 5 and 17 “are not limited to a specific carrier of which many are described in the specification” (Ans. 5), and therefore “read on liquid as well as solid compositions” (*id.*). “[R]egardless of initial form” (*id.*), the Examiner contends that “[o]nce in **liquid** solution, either polymorphic form would be indistinguishable with each other as well as claim 2 of US’467” (*id.*).

We agree with Appellants that claims 5 and 17 do not read on solutions comprising the salts of claims 3 and 4, respectively. The fact that the Specification discloses a variety of pharmaceutically acceptable carriers and excipients - some of which are capable of dissolving the salts of claims 3 and 4 - is irrelevant. Claims 3 and 4 require particular crystalline forms of 1-(Indole-6-carbonyl-D-phenylglyciny)-4-(1-methylpiperidin-4-yl) piperazine difumarate, and those crystalline forms are likewise required by dependent claims 5 and 17.

Again, the Examiner has not established that the particular crystalline forms of 1-(Indole-6-carbonyl-D-phenylglyciny)-4-(1-methylpiperidin-4-yl) piperazine difumarate required by claims 5 and 17 would have been obvious over the generic salt.

Therefore, the rejection of claims 5 and 17 under the doctrine of obviousness-type double patenting is reversed as well.

#### *Anticipation*

The Examiner also rejected claim 17 under 35 U.S.C. § 102(e) as anticipated by WO 01/96323.

The Examiner’s rationale here is similar to that of the obviousness-type double patenting rejection discussed above. Again, the Examiner

concedes that the crystalline form required by “claim 4 is not described or otherwise suggested by the WO disclosure” (Ans. 7), but contends that “once in **liquid** solution the polymorphic form would be indistinguishable from other forms of the difumarate salt including that of eg. [Example] 48B which is described in the WO publication” (*id.*).

Nevertheless, we agree with Appellants that claim 17 does not read on a solution comprising the salt of claim 4. The fact that the Specification discloses a variety of pharmaceutically acceptable carriers and excipients - some of which are capable of dissolving/dissociating the salt of claims 4 - is irrelevant. The fact that the salt of claim 4 would be indistinguishable from other forms of the difumarate salt once in a solution is similarly irrelevant. Claims 4 and 17 both require a particular crystalline form of the difumarate salt of 1-(Indole-6-carbonyl-D-phenylglyciny)-4-(1-methylpiperidin-4-yl) piperazine which the Examiner admits is not described in the prior art.

Accordingly, the rejection of claim 17 under 35 U.S.C. § 102(e) as anticipated by WO 01/96323 is reversed.

#### SUMMARY

The rejection of claims 3, 5, and 17 under the doctrine of obviousness-type double patenting is reversed.

The rejection of claim 17 under 35 U.S.C. § 102(e) as anticipated by WO 01/96323 is reversed.

REVERSED

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